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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/532,014	04/20/2005	Magnus Ingelman-Sundberg	25401-40	8991
24256 7590 04/19/2007 DINSMORE & SHOHL, LLP 1900 CHEMED CENTER 255 EAST FIFTH STREET CINCINNATI, OH 45202			EXAMINER DAVIS, MINH TAM B	
			ART UNIT	PAPER NUMBER
			1642	
SHORTENED STATUTORY PERIOD OF RESPONSE		MAIL DATE	DELIVERY MODE	
31 DAYS		04/19/2007	PAPER	

**Please find below and/or attached an Office communication concerning this application or proceeding.**

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

**Office Action Summary**

Application No.

10/532,014

Applicant(s)

INGELMAN-SUNDBERG ET AL.

Examiner

MINH-TAM DAVIS

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 21 December 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-10 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) 1-10 is/are objected to.
- 8) ☒ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                                | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

***DETAILED ACTION***

***Election/Restrictions***

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

**Group 1.** Claims 1-3, drawn to a binding agent or an antibody to CYP2W1 or SEQ ID NO:8.

**Groups 2-4.** Claim 4, drawn to a method for treating lung, colon, or ovarian tumor, using CYP2W1 protein. A method treating each cancer constitutes a single, distinct invention.

**Groups 5-7.** Claim 4, drawn to a method for treating lung, colon, or ovarian tumor, using CYP2W1 nucleic acid. A method treating each cancer constitutes a single, distinct invention.

**Group 8.** Claims 5-6, drawn to a method for screening agent that modulates CYP2W1 protein.

**Group 9.** Claims 5-6, 10, drawn to a method for screening agent that modulates CYP2W1 nucleic acid, or genes regulated by CYP2W1 promoter.

**Groups 10-12.** Claim 7, drawn to a method for treating lung, colon, or ovarian cancer, using a substance activated by CYP2W1 protein. A method treating each cancer constitutes a single, distinct invention.

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**Groups 13-15.** Claim 7, drawn to a method for treating lung, colon, or ovarian cancer, using an inducer of CYP2W1 protein. A method treating each cancer constitutes a single, distinct invention.

**Groups 16-18.** Claim 7, drawn to a method for treating lung, colon, or ovarian cancer, using binding agent of CYP2W1 protein. A method treating each cancer constitutes a single, distinct invention.

**Groups 19-21.** Claim 7, drawn to a method for treating lung, colon, or ovarian cancer, using a combination of a substance activated by CYP2W1 protein, and an inducer of CYP2W1 protein, or a combination of a substance activated by CYP2W1 protein, an inducer of CYP2W1 protein, and a binding agent for CYP2W1 protein. A method treating each cancer constitutes a single, distinct invention.

**Group 22.** Claims 8-9, drawn to a DNA molecule, SEQ ID NO:10.

The inventions are distinct, each from the other because of the following reasons:

According to PCT Rule 13.2, unity of invention exists only when the shared same or corresponding technical feature is a contribution over the prior art. The inventions listed as groups 1-22 do not relate to a single general inventive concept because they lack the same or corresponding special technical feature. The technical feature of group I, an antibody binding specifically to CYP2W1 protein, or SEQ ID NO:8, is shown to be the same as the antibody taught by WO 200290521-A2 ( Becha et al), or WO 200259260 A2 (Asundi et al), as evidenced by Banki et al, 1994, JBC, 269 (4): 2847-51, or Bendayan et al, 1995, J Histochem Cytochem,

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43(9): 881-886. Thus the invention of group I lacks novelty and does not make a contribution over the prior art.

WO 200290521-A2 teaches an antibody to the disclosed polypeptide, which is a human drug metabolizing enzyme (items 6, 14). The polypeptide taught by WO 200290521-A2 is 87% similar to SEQ ID NO:8, from amino acid 1 to amino acid 431 (MPSRCH search result, 2007, us-10-532-014.rag, result 2, pages 1-2).

MPSRCH search result, 2007, us-10-532-014.8.rag.

## RESULT 2

AAE33381

ID AAE33381 standard; protein; 464 AA.

XX

AC AAE33381;

XX

DT 02-APR-2003 (first entry)

XX

DE Human DME-7 protein.

XX

KW Human; drug metabolizing enzyme; DME; gastrointestinal disorder; asthma;  
KW peptic oesophagitis; peptic ulcer; Crohn's disease; autoimmune disorder;  
KW liver disorder; acquired immune deficiency syndrome; cataract; anaemia;  
KW inflammatory disorder; developmental disorder; achondroplastic dwarfism;  
KW Cushing's syndrome; endocrine disorder; diabetes insipidus; leukaemia;  
KW Sheehan syndrome; hypothyroidism; metabolic disorder; Addison's disease;  
KW glycogen storage disease; hypocalcaemia; conjunctivitis; pancreatitis;  
KW adenocarcinoma; cell proliferative disorder; actinic keratosis; cancer;  
KW arteriosclerosis; gene therapy; protein replacement therapy; lymphoma;  
KW eye disorder; sarcoma; obesity; melanoma; myeloma; AIDS; gout.

XX

OS Homo sapiens.

XX

FH Key Location/Qualifiers

FT Peptide

1. .28

FT /label= Signal\_peptide

FT Peptide 1. .24

FT /label= Signal\_peptide

FT Peptide 1. .22

FT /label= Signal\_peptide

FT Peptide 1. .20

FT /label= Signal\_peptide

FT Domain 4. .21

FT /note= "Transmembrane domain"

FT Protein 21. .464

FT /note= "Mature human DME protein"

FT Protein 23. .464

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FT /note= "Mature human DME protein"  
FT Protein 23. .464  
FT /note= "Mature human DME protein"  
FT Protein 25. .464  
FT /note= "Mature human DME protein"  
FT Domain 194. .222  
FT /note= "Transmembrane domain"  
XX  
PN WO200290521-A2.  
XX  
PD 14-NOV-2002.  
XX  
PF 10-MAY-2002; 2002WO-US015052.  
XX  
PR 10-MAY-2001; 2001US-0290430P.  
PR 08-JUN-2001; 2001US-0296880P.  
PR 22-JUN-2001; 2001US-0300472P.  
PR 29-JUN-2001; 2001US-0301794P.  
XX  
PA (INCY-) INCYTE GENOMICS INC.  
XX  
PI Ring HZ, Hafalia AJA, Sanjanwala MM, Yao MG, Zebarjadian Y;  
PI Edwards CM, Yue H, Tang YT, Lee EA, Emerling BM, Warren BA, Lal  
PG;  
PI Nguyen DB, Thangavelu K, Becha SD, Huang J, Ding L, Li JX;  
PI Griffin JA, Forsythe IJ, Richardson TW;  
XX  
DR WPI; 2003-111969/10.  
DR N-PSDB; AAD51048.  
XX  
PT New human drug metabolizing enzyme proteins and polynucleotides, useful  
PT for diagnosing, treating or preventing gastrointestinal (e.g. Crohn's  
PT disease) or autoimmune/inflammatory disorders (e.g. AIDS),  
hypothyroidism  
PT or cancer.  
XX  
PS Claim 1; Page 158-159; 175pp; English.  
XX  
CC The invention relates to human drug metabolizing enzyme (DME) proteins  
CC and nucleic acid molecules encoding such proteins. Sequences of the  
CC invention are useful for diagnosing, treating or preventing  
CC gastrointestinal disorders (e.g. peptic oesophagitis, peptic ulcer or  
CC Crohn's disease) including liver disorders, autoimmune/inflammatory  
CC disorders (e.g. acquired immune deficiency syndrome; AIDS, anaemia,  
CC asthma, gout, pancreatitis or Crohn's disease), developmental disorders  
CC (e.g. Cushing's syndrome or achondroplastic dwarfism), endocrine  
CC disorders (e.g. Sheehan syndrome, diabetes insipidus or hypothyroidism),  
CC eye disorders (e.g. conjunctivitis or cataract), metabolic disorders  
CC (e.g. Addison's disease, glycogen storage diseases, hypocalcaemia or  
CC obesity) or cell proliferative disorders (e.g. actinic keratosis,  
CC arteriosclerosis or cancers including adenocarcinoma, leukaemia,  
CC lymphoma, melanoma, myeloma, sarcoma or bone, ovary, lung, breast,  
CC prostate or skin cancer). The present sequence is human DME protein  
XX

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SQ Sequence 464 AA;

Query Match 87.8%; Score 2249; DB 6; Length 464;  
Best Local Similarity 99.5%; Pred. No. 6.1e-211;  
Matches 429; Conservative 2; Mismatches 0; Indels 0; Gaps  
0;

Qy 1 MALLLLLLFLGLLGLWGLLCACAQDPSPAARWPPGPRPLPLVGNLHLLRLSQQDRSLMELS 60  
|  
Db 1 MALLLLLLFLGLLGLWGLLCACAQDPSPAARWPPGPRPLPLVGNLHLLRLSQQDRSLMELS 60

Qy 61 ERYGPVFTVHLGRQKTVVLTGF EAVKEALAGPGQELADRPPIAIFQLIQRGGGIFSSGA  
120 |  
Db 61 ERYGPVFTVHLGRQKTVVLTGF EAVKEALAGPGQELADRPPIAIFQLIQRGGGIFSSGA  
120 |

Qy 121 RWRAARQFTVRALHSLGVGREPVADKILQELKCLSGQLDGYRGRPFPLALLGWAPSNITF  
180 |  
Db 121 RWRAARQFTVRALHSLGVGREPVADKILQELKCLSGQLDGYRGRPFPLALLGWAPSNITF  
180 |

Qy 181 ALLFGRRFDYRDPVFVSLGLIDEVMVLLGSPGLQLFNVYPWLGALLQLHRPVLRKIEEV  
240 |  
Db 181 ALLFGRRFDYRDPVFVSLGLIDEVMVLLGSPGLQLFNVYPWLGALLQLHRPVLRKIEEV  
240 |

Qy 241 RAILRTLLEARRPHVCPGDPVCSYVDALIQQGQDDPEGLFAEANA VACTLDMVMAGTET  
300 |  
Db 241 RAILRTLLEARRPHVCPGDPVCSYVDALIQQGQDDPEGLFAEANA VACTLDMVMAGTET  
300 |

Qy 301 TSATLQWAALLMGRHPDVQGRVQEELDRVLGPGRTPRLEDQQALPYTSAVLHEVQRFITL  
360 |  
Db 301 TSATLQWAALLMGRHPDVQGRVQEELDRVLGPGRTPRLEDQQALPYTSAVLHEVQRFITL  
360 |

Qy 361 LPHVPRCTAADTQLGGFLLPKGTPVIPLLTSVLLDETQWQTPGQFNP GHFLDANGHFVKR  
420 |  
Db 361 LPHVPRCTAADTQLGGFLLPKGTPVIPLLTSVLLDETQWQTPGQFNP GHFLDANGHFVKR  
420 |

Qy 421 EAFLPFSAGRR 431  
|::  
Db 421 EAFLPFSAGQQ 431

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WO 200259260 A2 teaches an antibody to the disclosed polypeptide. The polypeptide taught by WO 200290521-A2 is 75% similar to SEQ ID NO:8, from amino acid 57 to amino acid 431 (MPSRCH search result, 2007, us-10-532-014.rag, result 5, pages 2-4).

MPSRCH search result, 2007, us-10-532-014.8.rag

## RESULT 5

ABP64996

ID ABP64996 standard; protein; 408 AA.

XX

AC ABP64996;

XX

DT 25-FEB-2003 (first entry)

XX

DE Human protein SEQ ID 656.

XX

KW Human; expressed sequence tag; EST; haematopoietic disorder;

KW central nervous system disease; viral infection;

KW peripheral nervous system disease; non-healing wound; infectious disease;

KW immune deficiency; immune disorder; bacterial infection; allergy; cancer;

KW fungal infection; autoimmune disorder; coagulation disorder; nootropic;

KW antiallergic; antiinflammatory; immunosuppressive; neuroprotective;

KW cytostatic; haemostatic; virucide; antibacterial; fungicide;

KW immunostimulant; cerebroprotective.

XX

OS Homo sapiens.

XX

PN WO200259260-A2.

XX

PD 01-AUG-2002.

XX

PF 16-NOV-2001; 2001WO-US042950.

XX

PR 17-NOV-2000; 2000US-00714936.

XX

PA (HYSE-) HYSEQ INC.

XX

PI Tang YT, Goodrich RW, Liu C, Zhou P, Asundi V, Zhang J, Zhao QA;

PI Ren F, Xue AJ, Yang Y, Wehrman T, Drmanac RT;

XX

DR WPI; 2002-590824/63.

DR N-PSDB; ABQ99582.

XX

PT New isolated polynucleotide, useful in research, diagnostic or

PT therapeutic methods, e.g. preventing or treating disorders involving

PT aberrant protein expression or biological activity.

XX

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PS Claim 20; SEQ ID NO 656; 394pp; English.

XX

CC The present invention relates to novel human coding sequences (ABQ99268-  
CC ABQ99608) and proteins (ABP64682-ABP65022). The sequences are useful in  
CC therapeutic, diagnostic and research methods. The polynucleotides may be  
CC used in the field of molecular biology as hybridisation probes, primers  
CC for PCR, for chromosome and gene mapping, for the recombinant production  
CC of protein, or in generation of anti-sense DNA or RNA. The  
CC polynucleotides are useful in diagnostics as expressed sequence tags  
CC (ESTs) for identifying expressed genes or for physical mapping of the  
CC human genome. The proteins may be used as molecular weight markers, or  
as  
CC nutritional sources or supplements. The proteins may be used to maintain  
CC and expand cell population in a totipotent or pluripotent state  
CC useful for re-engineering damaged or diseased tissues, transplantation,  
CC manufacture of bio-pharmaceuticals or the development of bio-sensors.

The

CC polynucleotides and proteins are useful for preventing, treating or  
CC ameliorating disorders involving aberrant protein expression or  
CC biological activity, e.g. haematopoietic disorders, central/peripheral  
CC nervous system diseases, mechanical and traumatic disorders, non-healing  
CC wounds, immune deficiencies and disorders, infectious diseases caused by  
CC viral, bacterial or fungal infection, autoimmune disorders, allergic  
CC reactions and conditions, coagulation disorders, or cancer. The  
CC polynucleotide sequences of the invention were assembled from ESTs  
CC isolated mainly by sequencing by hybridisation, and in some cases,  
CC sequences obtained from one or more public databases. Note: The sequence  
CC data for this patent did not form part of the printed specification, but  
CC was obtained in electronic format directly from WIPO at  
CC ftp.wipo.int/pub/published\_pct\_sequences

XX

SQ Sequence 408 AA;

Query Match 75.9%; Score 1945; DB 5; Length 408;  
Best Local Similarity 99.2%; Pred. No. 3.2e-181;  
Matches 372; Conservative 3; Mismatches 0; Indels 0; Gaps

0;

Qy 57 MELSERYPVFTVHLGRQKTVVLTGFVAVKEALAGPGQELADRPPIAIFQLIQRGGGIF

116

Db 1 MELSERYPVFTVHLGRQKTVVLTGFVAVKEALAGPGQELADRPPIAIFQLIQRGGGIF 60

Qy 117 SSGARWRAARQFTVRALHSLGVGREPVADKILQELKCLSGQLDGYRGRPFPLALLGWAPS

176

Db 61 SSGARWRAARQFTVRALHSLGVGREPVADKILQELKCLSGQLDGYRGRPFPLALLGWAPS

120

Qy 177 NITFALLFGRRFDYRDPVFVSLGLIDEVMVLLGSPGLQLFNVYPWLGALLQLHRPVLRK

236

Db 121 NITFALLFGRRFDYRDPVFVSLGLIDEVMVLLGSPGLQLFNVHPWLGALLQLHRPVLRK

180

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Qy	237	IEEVRAILRTLLEARRPHVCPGDPVCSYVDALIQQGQGDDPEGLFAEANAVACTLDMVMA
296		
Db	181	IEEVRAILRTLLEARRPHVCPGDPVCSYVDALIQQGQGDDPEGLFAEANAVACTLDMVMA
240		
Qy	297	GTETTSATLQWAALLMGRHPDVQGRVQEELDRVLGPGRTPRLEDQQALPYTSAVLHEVQR
356		
Db	241	GTETTSATLQWAALLMGRHPDVQGRVQEELDRVLGPGRTPRLEDQQALPYTSAVLHEVQR
300		
Qy	357	FITLLPHVPRCTAADTQLGGFLLPKGTPVILLTSVLLDETQWQTPGQFNPGHFLDANGH
416		
Db	301	FITLLPHVPRCTAADTQLGGFLLPKGTPVILLTSVLLDETQWQTPGQFNPGHFLDANGH
360		
Qy	417	FVKREAFLPFSAGRR 431
		::
Db	361	FVKREAFLPFSAGQQ 375

The antibody taught by the art would bind to SEQ ID NO:8, or CYP2W1, which is interpreted as a variant of SEQ ID NO:8, as evidenced by Banki et al, which teach that an antibody against human transaldolase could bind to yeast transaldolase which is about 58% homologous with human transaldolase, i.e. an antibody could cross-react and bind to a polypeptide at least with 58% homology to its antigen (abstract), or Bendayan et al, which teach that anti-human proinsulin monoclonal antibody to the Arg-Arg dipeptide, although providing very specific binding results, cross-reacts with non-related molecules, i.e., rat, bovine, porcine and human glucagons (abstract).

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected

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invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MINH-TAM DAVIS whose telephone number is 571-272-0830. The examiner can normally be reached on 9:00 AM-5:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, SHANON FOLEY can be reached on 571-272-0898. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

MINH TAM DAVIS  
April 12, 2007

  
SHANON FOLEY  
SUPERVISORY PATENT EXAMINER  
TECHNOLOGY CENTER 1600